MADSEN AccuScreen®

AccuScreen
OAE & ABR Screener

User Manual

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Technical support
Please contact your supplier.

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OAE & ABR Screener

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1 Introduction

Thank you for purchasing the AccuScreen handheld Otoacoustic Emissions and Automated ABR Screener.

Note · *This manual is your guide to the use and maintenance of AccuScreen. We strongly recommend that you read it carefully before using AccuScreen for the first time.*

We also recommend that you take particular note of the cleaning and maintenance instructions. Failure to use and maintain AccuScreen correctly may void your warranty.

AccuScreen is a fast, reliable, easy to use, and lightweight hearing screener, optimised for neonatal screening. AccuScreen closes the gap between electrophysiological assessment, which is time-consuming and expensive, and behavioral observation.

AccuScreen provides for easy navigation using its touch screen function.

AccuScreen uses TEOAE (Transiently Evoked Otoacoustic Emissions) and DPOAE (Distortion Product Otoacoustic Emissions) technologies, which are highly effective for neonatal hearing screening. Otoacoustic Emissions measure cochlear mechanics and indicate whether the cochlea is functioning correctly or not. Children's emissions are typically strong, which makes them easy and fast to detect. Emission strength usually decreases with age.

Automated ABR (Auditory Brainstem Response) is also available in AccuScreen. This technology measures responses to sound in the auditory pathways. It provides a valuable supplement to TEOAE and DPOAE screening, and is an essential tool for screening infants with a risk of hearing loss.

The simple yet reliable technology ensures that hearing loss can be detected and that intervention can be implemented at an early age. With early intervention, hearing-impaired children are given the possibility of developing normal speech and language skills.

1.1 The different versions of AccuScreen

AccuScreen is available in different configurations.

You can choose between the following types and test methods:

Device type	Test types	Part no.
AccuScreen TE	TEOAE	8-04-13900
AccuScreen DP	DPOAE	8-04-13901
AccuScreen TE/DP	TEOAE and DPOAE	8-04-13902
AccuScreen ABR	ABR	8-04-13903
AccuScreen ABR/TE	ABR and TEOAE	8-04-13904
AccuScreen ABR/DP	ABR and DPOAE	8-04-13905
AccuScreen ABR/TE/DP	ABR, TEOAE and DPOAE	8-04-13906

1.2 The AccuScreen docking station

The AccuScreen is supplied with a docking station, which provides for:

- easy recharging of the battery
- transferring data between device and PC
- printing from a label printer
- transferring data via modem

1.3 The AccuLink software program

AccuLink is a software program providing data management handling with result review and configuration capabilities in a single PC application.

From AccuLink you can create, edit, view and print data relating to patients and tests, users, sites and connected locations and facilities.

From AccuLink you can configure AccuScreen to suit your purposes. This includes defining mandatory fields in patient handling, defining which screens are to be shown in AccuScreen, and uploading and downloading data.

AccuScreen is operated independently of AccuLink, although additional features and configuration value are offered by AccuLink's user interface.

1.4 Printing

For printing instructions see 7 Printing ▶ 61.

AccuScreen
With AccuScreen you can upload data to AccuLink and print test results from the AccuLink PC, or you can place AccuScreen in the docking station and print directly to a label printer connected to the docking station.

1.5 Intended Use

AccuScreen is a portable instrument used to screen infants for hearing loss. The instrument uses the Distortion Product Otoacoustic Emissions (DPOAE), Transient Evoked Otoacoustic Emissions (TEOAE) and Auditory Brainstem Response (ABR) technologies.

The instrument is intended for screening infants from 34 weeks (gestational age) up to 6 months of age that are well enough to be ready for discharge from the hospital. Infants should be asleep or in a quiet state at the time of screening.

AccuScreen is intended for use by audiologists, ENTs and other health care professionals.

Important · *GN Otometrics A/S does not guarantee the accuracy of the test results or the tests themselves, if accessories other than those supplied by GN Otometrics A/S are used for this device (i.e. eartips, electrodes, ear couplers, etc.).*

1.6 About this manual

Important · *Please note that menu selections and screen shots in this manual may not reflect the configuration of your test device.*

This manual contains a description of the main functions of AccuScreen.

We recommend that you make yourself familiar with the following issues:

Installation
2.1 Unpacking AccuScreen ▶ 13, and 4 Preparing for testing ▶ 29 contain a full description of unpacking instructions, controls and socket connections, and how to install the device and software.

Safety

This manual contains information and warnings which must be followed to ensure the safe performance of AccuScreen. Local government rules and regulations, if applicable, should also be followed at all times.

Please see the overview of device labeling in 2.2.1 Front and rear view ▶ 13 and read the warning notes in App. 1 Standards and Safety ▶ 89.

Training

It is recommended that you read this manual before you start operating AccuScreen so that you become familiar with the device before testing on a client.

Maintenance and cleaning

For instructions on how and when to clean AccuScreen and accessories, please see 11 Maintenance and Cleaning ▶ 83.

1.7 Typographical conventions

The use of WARNING, CAUTION and NOTE

For safety reasons and appropriate use of AccuScreen, the manual contains **Warnings**, **Cautions** and **Notes**, which you should read carefully. They are used as follows:

Warning · *Indicates that there is a risk of danger to persons and device.*

Caution · *Indicates that there is risk of damage to the device.*

Note · *Indicates that you should take special notice.*

1.7.1 Navigating this manual

Menus, icons and functions to select are shown in bold type, as for instance in:

- Press the **OK** button.

2 Unpacking and Installation

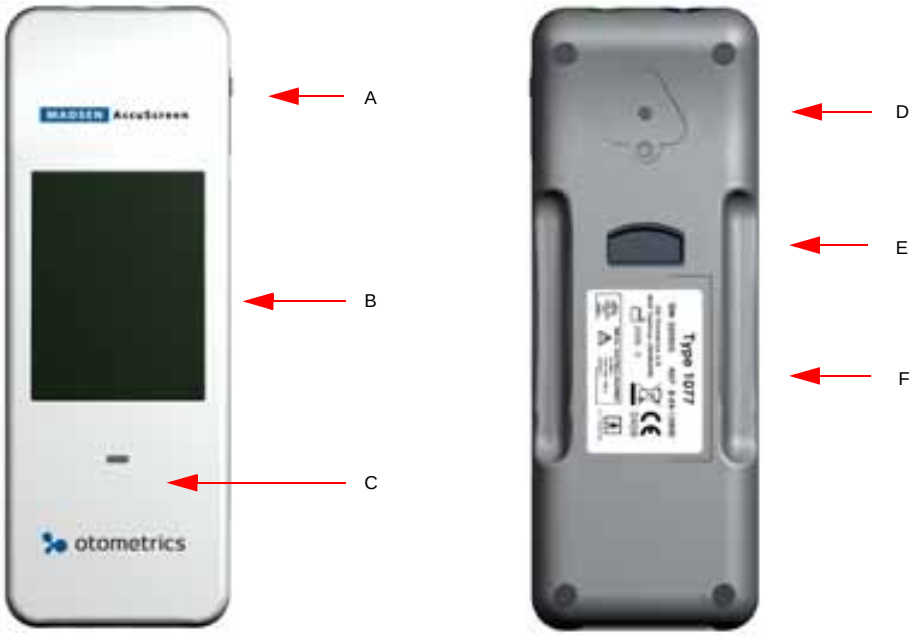
2.1 Unpacking AccuScreen

- Unpack AccuScreen carefully.
- Visually inspect the equipment for possible damage.
- Make sure that you have received all necessary parts and accessories.
  If your package is incomplete, contact your supplier.

Caution · *If damage has occurred, do not put the device into operation. Contact your supplier for assistance.*

2.2 Views of AccuScreen

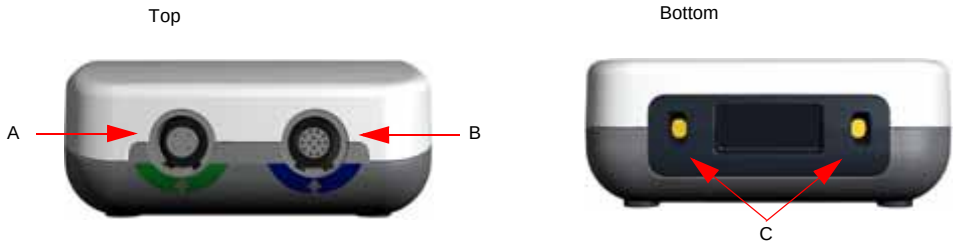
2.2.1 Front and rear view



A. On/Off switch
B. Touch screen display

C. Power and charging status light indicator
D. Test cavity
E. Button for opening battery compartment
F. Cover on battery compartment with serial number label

2.2.2 Top and bottom view



A. ABR socket

B. Probe socket & ear coupler cable socket

C. Docking Station connectors

2.2.3 The docking station

Front indicators	
	POWER Lit when the mains power supply to the docking station is on.
	Lit when data is being transferred: • during transfer of data between AccuScreen and AccuLink. • during printing from label printer
	USB Lit when docking station is connected to the PC via a USB cable.

Rear sockets	
	PC/USB Socket for USB connection to the PC
	Printer/Modem Socket for printer/modem connection
	Socket for power adapter

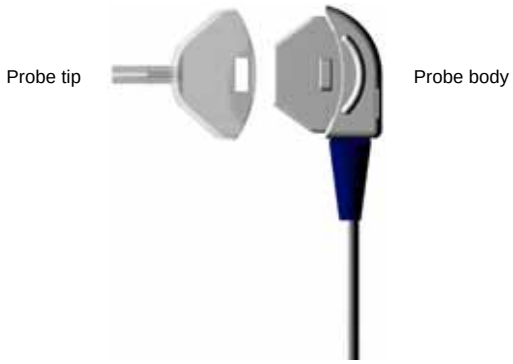
2.2.4 Display

The display is a touch-screen display, where the icons and fields shown serve as buttons.

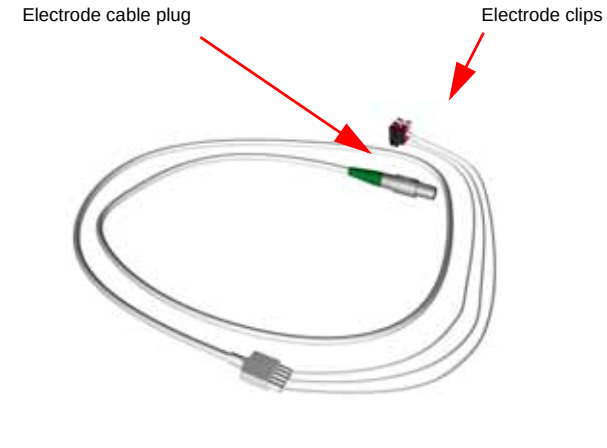
- Touch the buttons to activate a function.

Caution · *Never use any type of sharp instrument on the display. If you do, reliable operation of AccuScreen can no longer be guaranteed.*

2.2.5 Ear probe



2.2.6 Electrode cable (ABR only)



2.3 Storage

Store AccuScreen and accessories in the soft case provided to protect the equipment from damage. See also App. 3.3.15 Operating environment ▶ 103.

2.4 Assembly

When you receive AccuScreen, you must insert the battery in the battery compartment. See 2.5.2 Inserting the battery in AccuScreen ▶ 18.

- We recommend that you charge the battery fully by placing AccuScreen in the docking station (2.5.5 Charging the battery from the docking station ▶ 20).
- For testing purposes, fit the probe, the ear coupler cable and the electrode cable as needed. See 4 Preparing for testing ▶ 29.

2.5 Powering

AccuScreen is powered by a rechargeable battery. The battery is charged:

- when AccuScreen is placed in the docking station. See 2.5.5 Charging the battery from the docking station ▶ 20.
- by the AccuScreen external charger (optional accessory). See 2.5.6 Charging the battery with the external charger ▶ 20.

2.5.1 The battery

The battery used in AccuScreen:

- is a rechargeable Li-Ion battery, Part no. 8-73-02400
- has a high capacity
- is low weight
- has a low rate of self discharge
- can be charged continuously
- guarantees approximately 8 hours of operating time

On delivery, the battery is charged approx. 50%.

Before you start testing, we recommend that you charge the battery fully.

Use only the battery type, docking station and charger stated in App. 3.4 Power supply and battery ▶ 104 and App. 3.5 1077 docking station (optional accessory) ▶ 104.

See 11.5 Battery safety and maintenance ▶ 86.

Battery Storage

If the battery is to be stored for a long time, it is recommended that it is stored with approximately 50% remaining battery capacity and in a dry and cool place. Storing the battery in a refrigerator can be recommended.

If the battery is stored with full battery capacity and at room temperature or warmer, the battery will permanently degrade with about 10-20% after one year.

2.5.2 Inserting the battery in AccuScreen

1. Push the button of the battery compartment upwards.
   The battery compartment pops out.

2. If needed, remove the battery.

3. Place a new, charged battery in the compartment.
   – Hold the battery so that the arrow with the text “Insert this direction” points downwards towards the bottom of the compartment.
4. Close the compartment.

2.5.3 Battery status

- The battery symbol is shown in the top right corner of the display, enabling you to view the status of the battery at all times.
- When less than 25% of the battery capacity remains, we recommend that you change the battery and recharge it as soon as possible.
- When the battery level drops below 10%, test results can be viewed, but testing is no longer possible.

Symbol	Remaining battery capacity	
	100 - 75%	Battery is fully charged.
	75 - 50%	
	50 - 25%	
	25 - 10%	Battery should be charged.
	10 - 0%	Battery is very low and testing is not possible.

If the necessary minimum voltage should drop, AccuScreen switches off automatically. Recharge or change the battery as soon as possible.

2.5.4 Powering the docking station

The AccuScreen docking station is powered through an adapter from the mains outlet.

Warning · *In order to comply with the safety requirements for a medical device system, connection to the docking station must always be done outside the patient area (min. 1.5 meters/5 ft from the patient).*

You will find an adapter plug kit when you unpack AccuScreen. The adapter plug kit contains a range of adapter plugs you can choose from to fit your mains outlet.

Connecting to the mains supply

1. Select the adapter plug appropriate to your mains outlet and fit it on the adapter.
2. Connect the adapter to the docking station and the mains supply, and switch on the mains supply. The **POWER** indicator will light up green.

Disconnecting from the mains supply

To disconnect AccuScreen docking station from the mains supply, simply remove the adapter plug from the mains outlet.

2.5.5 Charging the battery from the docking station

The battery in AccuScreen charges automatically when you place AccuScreen in the docking station.

1. Place AccuScreen in the docking station.
   The light indicator on the front of AccuScreen will light up.

Front light indicator	
Green	• Fully charged
Orange - steady	• Charging
Orange - flashing	• During start-up • When there is a battery error, for example: – No battery inserted – Battery inserted incorrectly – Defect battery

Charging a fully discharged battery from the docking station takes approximately:

80% charged	4½ hours
Fully charged	6 hours

2.5.6 Charging the battery with the external charger

Caution · *Use only the charger supplied by GN Otometrics A/S.*

The battery for AccuScreen can be charged by an external charger (optional accessory).

See the charger manufacturer's documentation for specifications and instructions for use.

3 Getting Started with AccuScreen

In the following, you will find quick instructions for getting started with AccuScreen:

- Switching on AccuScreen
- Adding new patients
- Finding patients
- Editing patient data

You will find in-depth instructions for preparing and testing in:

- 4 Preparing for testing ▶ 29
- 5 Tests ▶ 37

3.1 Switch on AccuScreen

1. Switch on AccuScreen: Press the **On/Off** switch.

   A start-up screen is shown, while AccuScreen performs a self-test.

   The start-up screen shows the name of the device.

   The AccuScreen name is configurable (see the AccuLink User Manual).

3.1.1 Power-saving mode and automatic power-off

If you do not use AccuScreen for a certain period of time, AccuScreen will first switch to power-saving mode, and finally switch off automatically. These periods are configurable (see the AccuLink User Manual).

- When AccuScreen is in power-saving mode, the display goes black and the power indicator lights up green.
- Simply touch the screen to reactivate AccuScreen.

3.1.2 The AccuScreen screens

Important · *The screens shown in your AccuScreen depend on the configuration of AccuScreen. In the following, the default selection and sequence of screens is shown. This is configurable; see the AccuLink User Manual.*

- Main instructions for data entry screens are described in
  - 10.1 Entering data in AccuScreen ▶ 77.
- Buttons are described in
  - 10.2 Function buttons ▶ 78
  - 10.3 General buttons ▶ 79

Navigating the screens in AccuScreen

The screens in AccuScreen are usually divided into 3 or 4 main areas:

A. The title bar, showing
- the time
- the screen title
- the battery status

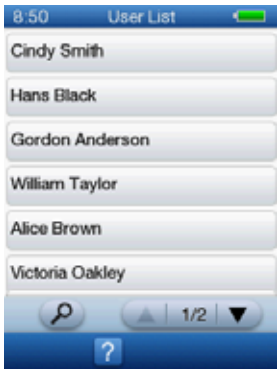
B. The main screen where you will typically find
- test screens
- patient buttons
- keypad for entering data, etc.

C. The function bar with available function buttons

D. The footer with available buttons for main functions such as
- returning to the previous screen,
- accessing help,
- returning to the **Home** screen.

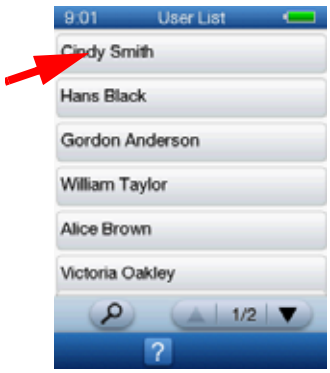
3.1.3 Selecting the user

1. Select a user from the **User List**.
   The **User List** is configurable (see the AccuLink User Manual).



3.1.4 Entering password

1. In the **Password** screen you will be prompted for a password.
   – To enter your password, select the characters and/or digits from the keypad.
   Passwords and the use of passwords are configurable (see the AccuLink User Manual).



2. Press the **OK** button to activate your password.

3.1.5 Incorrect password

If you enter your password incorrectly 3 times in a row, AccuScreen will be locked and cannot be used by you.

The system administrator can unlock AccuScreen from AccuLink.

Another user can log into AccuScreen. This means that only the user with the 3 incorrect attempts is locked out.

1. Launch AccuLink.
2. Place AccuScreen in the docking station to unlock. When a predefined period of time has expired, AccuScreen unlocks automatically.
   The duration is configurable (see the AccuLink User Manual).

3.1.6 Optional screens

The following screens are optional, and not part of the default AccuScreen configuration.

The **Location** list is configurable (see the AccuLink User Manual).

The **Facility List** is configurable (see the AccuLink User Manual).

3.1.7 The Home menu

The Home menu

From the **Home** menu, you can select all main functions in AccuScreen.

- See 3.2.2 Finding a patient ▶ 26.

- See 3.2.1 Adding a new patient ▶ 25.

- See 5.6 Test view ▶ 56.

- See 7 Printing ▶ 61.

- See 10.4 Deleting data ▶ 79.

- See 6 Quick Test ▶ 59.

- See 8 Quality Tests ▶ 67.

- See 9 AccuScreen settings ▶ 73.

3.2 Patient handling in AccuScreen

Note · *If you wish to perform a* **Quick Test**, *adding or finding a patient is not necessary.*

You can download patient data in advance from AccuLink (see the AccuLink User Manual for instructions).

3.2.1 Adding a new patient

1. To add a new patient, press the **New Patient** button on the **Home** menu.

   The **New Patient** screen shows a list of buttons you can press to select screens for entering patient data.

   There are two types of fields for data entry:

   – *Mandatory fields*

   In mandatory fields the text **Press to edit** is shown in red.

Note · *You must always enter a value in the mandatory fields.*

   Mandatory fields are defined in AccuLink (see the AccuLink User Manual).

   – *Optional fields*

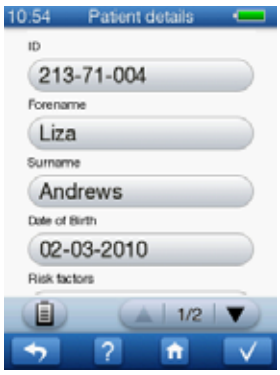
   Press the first mandatory field to enter patient data.

   When you have entered data in a field, press the **OK** button and then press the next button in the list.

2. To view more fields in the **New Patient** screen, press the arrow buttons.

3. When you have entered data in all mandatory fields and press the **OK** button, the data is saved, and the **New Patient** screen is shown.

This screen enables you to view and, if needed, add data in optional fields or change the entered data.



Regular data entry screens

In most of the screens, simply use the keypad to enter data. For more information, see 10.1.1 Using the keypad ▶ 77.

- The **ID** screen
- The **First Name** screen
- The **Last Name** screen

Special data entry screens

Screens with special data entry features are described in the following.

The Date of Birth screen

In the **Date of Birth** screen, press the arrow buttons to set the correct date of birth.

DD = Day
MM = Month
YYYY = Year

- If you pass the end or the beginning of a month in the day (DD) column, the **MM** value is stepped up or down accordingly.
- If you step up the **MM** value to 01, (i.e. to a new year) the **YYYY** value is stepped up accordingly.

3.2.2 Finding a patient

1. To find a patient, press the **Find Patient** button on the **Home** screen.

   This will take you to the **Find Patient** screen.
2. If needed, press the arrow buttons to scroll in the list of patients.

3. Select the patient from the list.

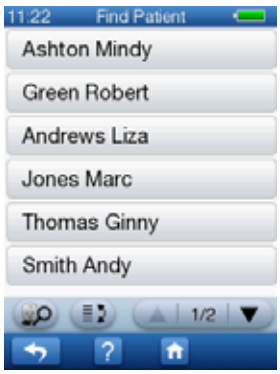
Searching in an extended patient list

1. To search in an extended list of patients, press the **Find Patient** button in the **Find Patient** screen.

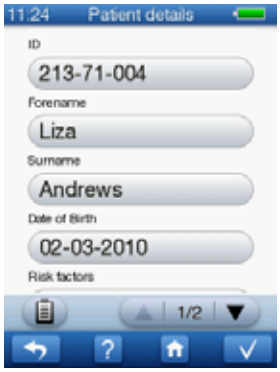
2. Enter the patient's last name.
   If needed, see 10.1.1 Using the keypad ▶ 77.
3. If you wish to change your search criteria in order to limit your search further, press the **Search Criteria** button. If needed, press repeatedly until you see the category you wish to use.

4. Press the **OK** button to start the search.
   The search will produce a list of patients matching the search criteria.

5. Press the button showing the name of the patient you wish to select.



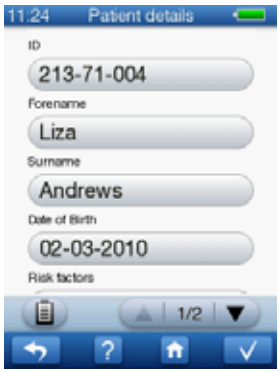
   The **Patient Details** screen is shown.



6. If you wish to view the tests performed on the patient, press the **Test View** button.

3.2.3 Editing patient data

1. Find a patient as described in 3.2.2 Finding a patient ▶ 26.
2. In the **Patient Details** screen press the field you wish to edit.
3. Edit the field.



4. When you have edited data in a field, press the **OK** button to save.

5. If needed, select the next field you wish to edit.

4 Preparing for testing

4.1 Preparing AccuScreen

- Follow the instructions in 3 Getting Started with AccuScreen ▶ 21.
- You can download patient data in advance from the AccuLink database (see the AccuLink User Manual).
- See 5 Tests ▶ 37 on how to proceed with the specific tests.

4.2 Preparing the equipment

Every day before you start testing on patients, we recommend that you perform whichever quality tests that may be necessary to make sure that probe, electrode cable and ear coupler cable function correctly. See 8 Quality Tests ▶ 67.

4.2.1 Preparing the probe for testing

Caution · *Insert only disinfected probe tips in the test cavity. See 11.4.1 Cleaning and disinfecting the test cavity ▶ 85.*

Every day before you start testing on patients, you should test the probe to make sure that it functions correctly.

See 8.2 Probe test ▶ 67.

4.2.2 Connecting the probe

1. Place AccuScreen face down.
   The probe plug sleeve and the coloring around the probe socket are blue.
2. Align the double arrow on the probe plug with the arrow in the blue bordering around the socket of AccuScreen.
3. Gently insert the probe plug into the probe socket on top of AccuScreen. The plug does not require force to be inserted properly.

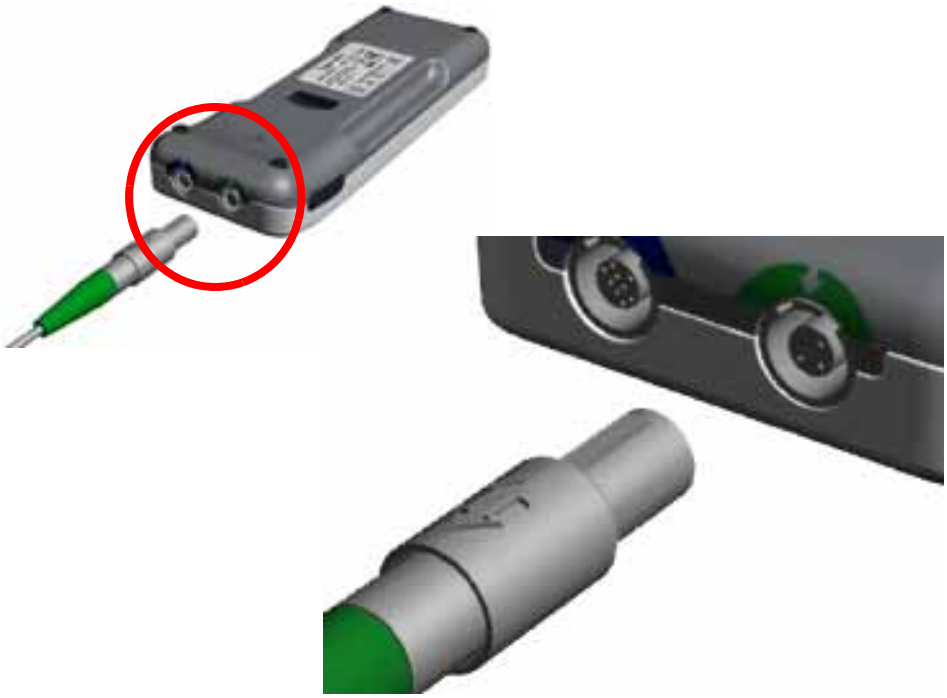
Disconnecting the probe

Caution · *Do not pull the plug by the cable when you disconnect the probe.*

To disconnect do not twist the plug. Instead, hold the sleeve of the plug and release it by pulling it straight out of the socket.

The probe will not be released if you pull anywhere else than on the sleeve of the plug.

4.2.3 Connecting the electrode cable for ABR testing



1. Place AccuScreen face down.
   The electrode cable plug sleeve and the coloring around the probe socket are green.
2. Align the double arrow on the electrode cable plug with the arrow in the green bordering around the socket of AccuScreen.
3. Gently insert the electrode cable plug into the electrode cable socket on top of AccuScreen. The plug does not require force to be inserted properly.

Disconnecting the electrode cable

Caution · *Do not pull the plug by the cable when you disconnect the electrode cable.*

To disconnect do not twist the plug. Instead, hold the sleeve of the plug and release it by pulling it straight out of the socket.

The cable will not be released if you pull anywhere else than on the sleeve of the plug.

4.2.4 Connecting the ear coupler cable for ABR testing

For ABR-measurements you can use either the ear probe or the ear coupler cable with ear couplers. A major advantage in using the ear coupler cable is that once the test starts, both ears can be tested consecutively.

1. Place AccuScreen face down.
   The sleeve on the plug of the ear coupler cable and the coloring around the probe socket are blue.
2. Align the double arrow on the plug with the arrow in the blue bordering around the socket of AccuScreen.
3. Gently insert the plug into the probe socket on top of AccuScreen. The plug does not require force to be inserted properly.

Disconnecting the cable

Caution · *Do not pull the plug by the cable when you disconnect the ear coupler cable.*

To disconnect do not twist the plug. Instead, hold the sleeve of the plug and release it by pulling it straight out of the socket.

The cable will not be released if you pull anywhere else than on the sleeve of the plug.

4.3 Preparing the test environment

Physical environment

- Make sure that the test environment is as quiet as possible. The quieter the room is, the more accurate and quick your testing will be.
- Check that testing is not being done under an air conditioner or in front of a fan or ventilator.
- Check that there are no mobile phones in the vicinity, people talking etc.

Hygienic precautions

- Be sure to follow any established infection control procedures for the setting in which you are working.
- Always use new eartips.
- Swab the probe tip with a disinfectant between babies, or replace it with a spare one.

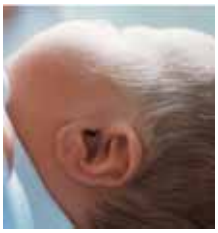
4.4 Preparing the patient

Newborn hearing screening

Newborn hearing screening with OAE and ABR is best performed when the baby is sleeping. The ideal time is after the baby has been fed and changed.

It is recommended that newborn babies be swaddled tightly for ABR testing. Swaddling has a very calming effect.

4.4.1 Prepare the patient for TEOAE and DPOAE testing



General preparations of the patient

1. Position the patient so that you can easily access the ear to be tested.
2. Grasp the pinna and gently pull back and slightly away from the patient's head.
3. Look into the ear canal.

   If you can see apparent narrowing of the ear canal, it probably is not straight.

   Because newborn ear canals are very soft, they are easily pressed out of shape. If this is the case, wait until the ear canal returns to its original shape.

   Release the pinna and try again. Gently massaging the area may help opening the ear canal.
4. Inspect the ear canal to make sure it is clear of vernix or debris as this may affect the result of the test. Clean the ear canal if required.

4.4.2 Fitting the eartip on the probe

1. Select an ear tip that fits the patient's ear canal. You may have to try out a number of sizes in order to select the appropriate size.
2. Gently push the eartip onto the probe tip until it rests firmly against the base of the probe. It is much easier to attach and remove the eartip if you turn it gently. When you do so, make sure that you hold the probe by the probe body and *not by the cable*.

Note · *Accurate testing is only guaranteed if you use the eartips provided.*

Note · *The probe can be used for both ears. If you suspect infection in one ear, change the eartip and clean the probe tip, or replace it with a spare, before you continue testing on the other ear.*

Warning · *Using a probe with an unsuitably sized eartip or applying excessive force may irritate the ear canal.*

Note · *In case of a probe error, make sure that the probe tip channels are clear (see 11.1 The probe tip and probe body ▶ 83) and that the probe is connected.*

See also 8.2 Probe test ▶ 67.

4.4.3 Inserting the probe with eartip in the patient's ear canal

1. When you have fitted an eartip on the probe, gently pull the pinna back and slightly down and insert the probe in the ear canal, twisting the probe slightly as you insert it.

   The probe can be inserted with the probe cable pointing either upwards or downwards, depending on which direction fits best.

   Make sure that the probe fits well. Any leakage may increase the test duration because of distortion and excessive noise.

Note · *Make sure that the cable is not in contact with any vibrating surfaces during testing.*

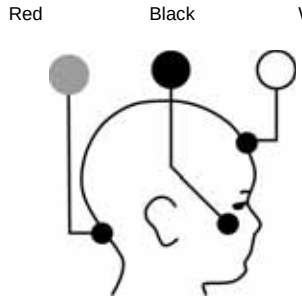
2. If you have selected an ABR test, you must also fit the electrodes correctly. See 4.4.4 Placing electrodes for ABR testing ▶ 35.

4.4.4 Placing electrodes for ABR testing

Skin preparation

Note · *Do not use alcohol pads or other cleaning agents that contain alcohol to prepare the skin as they may cause the skin to dry out, leading to a higher skin impedance.*

1. Place the electrodes on the patient as follows:



●	Red	On the nape of the neck
●	Black	On the cheekbone (reference electrode)
○	White	High on the forehead

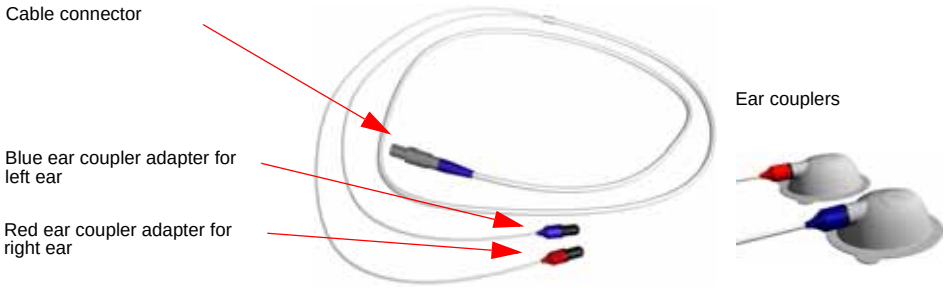
2. Make sure that the electrodes fit tightly on the skin.

Note · *The hydrogel of the electrodes can dry out. Make sure that used packages are closed properly. Dried out hydrogel may cause unexpectedly high electrode impedance. If this is the case, change the electrodes.*

4.4.5 Fitting the ear couplers

Warning · *Never place the red and blue ear coupler adapters directly in the ear canal. Use them only with the ear couplers fitted.*

Note · *Use the ear couplers only with the ear coupler cable - not with the ear probe.*



1. Place the electrodes on the forehead, neck and cheek bone of the baby, before you connect the ear couplers. See 4.4.4 Placing electrodes for ABR testing ▶ 35.
2. Insert an ear coupler adapter into the tube at the top of each ear coupler.
3. Peel off the protective film of the ear coupler.
4. Place the ear coupler with the red adapter over the right ear of the baby, and the ear coupler with the blue adapter over the left ear of the baby.

The ear couplers can be placed with the cables pointing either upwards or downwards, depending on which direction fits best.

Caution · *To remove the ear coupler cables, do not pull them by the cable. Instead, hold them by the transducer.*

5 Tests

The following describes the tests available in AccuScreen.

1. Decide on which ear you wish to perform the test.
2. Do as described in 4 Preparing for testing ▶ 29.

The test, as it progresses, is described in:

- 5.2 The TEOAE test ▶ 38.
- 5.4 The DPOAE test ▶ 45
- 5.5 The ABR test ▶ 50

5.1 Ready to test

You can choose between two methods of testing:

- Quick testing
- Regular testing

Quick testing

1. Select **Quick Test** from the **Home** screen.
   The test selection depends on the device type, the configuration of the device, and which cables are connected.
2. Press the **Start** button corresponding to the ear you wish to test. See the test descriptions in:
   - 5.2 The TEOAE test ▶ 38.
   - 5.4 The DPOAE test ▶ 45
   - 5.5 The ABR test ▶ 50

Note · *These test results are not stored.*

Regular testing

1. Find a patient (3.2.2 Finding a patient ▶ 26) or add a new patient (3.2.1 Adding a new patient ▶ 25).
2. Press the **OK** button in the **New Patient** screen or the **Patient Details** screen.
3. This will take you to the patient's **Test Menu**.

   The test selection depends on the device type, the configuration of the device, and which cables are connected.

   Selecting available tests is configurable (see the AccuLink User Manual).
4. See the test descriptions in:
   - 5.2 The TEOAE test ▶ 38.
   - 5.4 The DPOAE test ▶ 45
   - 5.5 The ABR test ▶ 50

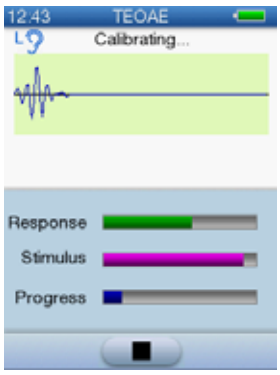
5.2 The TEOAE test

5.2.1 Starting the test

1. To start the test, press the **Start** button that is next to **TEOAE**, and that corresponds to the ear in which you placed the probe.

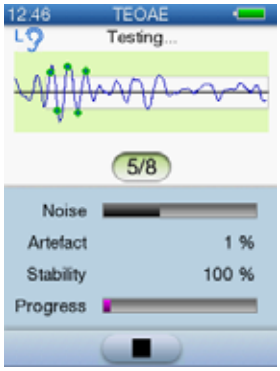
Calibration is performed before the actual test starts.

The test starts automatically when calibration is completed.



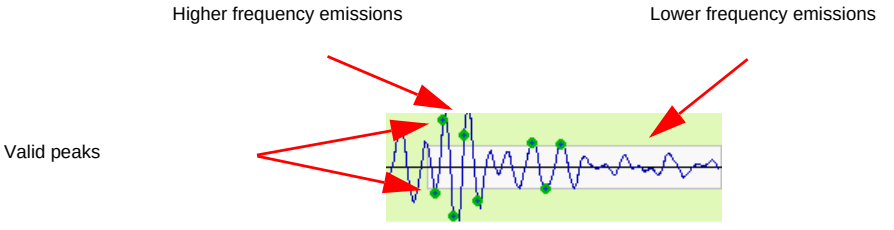
5.2.2 The TEOAE test

The test as it progresses is shown on the display.



- If needed, press the **Stop** button to stop the test. The test will be saved as an incomplete test.

Test details	
	Shows which ear is being tested.



The graphic display shows the peaks reaching the test criteria. The graph is a statistical graph.

Test details	
	Valid peak Shows that the intensity of a peak is valid and counted by the peak counter.
	Peak counter The test must register a total of at least 8 valid peaks in alternating directions (counted both above and below the median line) in order to lead to a PASS (Test passed).
	Noise Current noise level. Make sure the **Noise** level is as low as possible. A high **Noise** level may indicate a high level of environmental noise or a noisy baby.
	Artifact Shows the average artifact level in percent. The artifact rate (emanating from noise) should be below 20%, if possible. If artifacts are present, this may indicate a high level of environmental noise or a noisy baby. In these cases, check the test conditions and make sure that the probe fits.
	Stability Shows the average probe stability level in percent. The stimulus stability (emanating from probe stability) should be above 80%, if possible.
	Progress Shows the test progress. Max. time depends on environmental noise conditions. When the blue bar reaches the end, the test is completed.

Test duration for babies
Less than 10 seconds on babies with normal hearing under quiet conditions, but highly dependent on test conditions in general.

5.2.3 TEOAE test results

When the test is completed, the test data is saved and the result is shown on the screen.

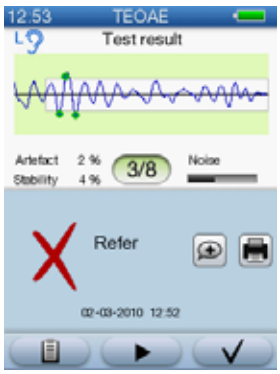
- Press the **OK** button to return to the **Test Menu**.

PASS (Test passed)

If the result is a *PASS (Test passed)*, just the graph is shown.

- A *PASS (Test passed)* result indicates that the patient has normal outer hair cell function at the time of testing.
- A *PASS (Test passed)* is determined by a statistical algorithm, based on weighted averaging, which ensures detection with proven high specificity and sensitivity. No further interpretation of a *PASS* result is needed.

REFER (Test referred)



If the result is a *REFER (Test referred)*, the detailed results are shown immediately below the graph.

REFER (Test referred):

- A *REFER (Test referred)* is "good" when the **Artifact** and **Stimulus** levels do not exceed the critical limits (see below), indicating that test conditions were good.
- A *REFER (Test referred)* is "bad" when the **Artifact** and **Stimulus** levels have been exceeded, indicating that test conditions were not optimal. In this case the patient should be retested.

A *REFER (Test referred)* result may occur for a number of reasons, the most important one being that the patient may have a sensorineural hearing loss.

Always consider the factors below, however, when you interpret a *REFER (Test referred)* result. It may be possible to improve the quality of the test and so, on repeating the test a *PASS (Test passed)* may be obtained. It is always recommended that you repeat the test when a *REFER (Test referred)* result is obtained.

Consider for instance the following when you interpret a *REFER (Test referred)* result:

- Malfunctions in the transmission of sound are by far the most important causes of emissions not being detected. To eliminate this possibility, always make sure

that the probe tip and the ear canal are not blocked by cerumen or vernix. Clean the probe, change the eartip, and then repeat the test.

- It is recommended that you repeat the test if the test conditions were not optimal (too much noise, too restless a patient, etc.). If required, use a sound cabin or a room, where the ambient noise is as low as possible.

Artifact and Stimulus values

If the **Artifact** value (artifact reject) is greater than 20%, this may indicate a noisy test. Try to improve test conditions and repeat the test.

If the **Stimulus** value (stimulus stability) is less than 80%, the probe may have shifted or may not be in a position to record the response. Try to reposition the probe and repeat the test.

Note · *Retro-cochlear hearing loss cannot be detected by TEOAE testing.*

Incomplete test

If the test was stopped, an error message and detailed results are shown.

The result screen appears differently if the test failed or was aborted during calibration.

5.2.4 Options in the test result screens

Test result options	
	Comments If you wish to add comments to the test results, press the **Comments** button. This will take you to the **Comments** screen, where you can select predefined comments or add your own comments. See 5.3 Adding comments to a test ▶ 44.
	Print results See 7 Printing ▶ 61.

Test result options	
	Test View See the tests performed on the patient, 5.6 Test view ▶ 56.
	Start If you wish to repeat the test, press the **Start** button.
	OK Press to return to the **Test Menu**, so that you can test the other ear or continue with another type of test.

1. Press the **OK** button to return to the **Test Menu**.

   When the test is completed for a specific ear, the **Start** button changes to show the result.

   The buttons show the best, most recent test. Press the specific button to view the result.

   – **PASS**

   – **REFER**

   – **Incomplete**

2. The **Binaural test** button for ABR testing, if shown, does not change. Pressing it will start a new binaural test.

5.2.5 Continuing testing on the other ear

1. Before you continue testing the other ear, check to make sure that the probe is clean. See also 11.1 The probe tip and probe body ▶ 83.
2. If needed, reposition the patient so that you can test the other ear and insert the probe in the new test ear.
3. Select the patient's other ear on the **Test Menu**.
4. Start the test.

5.3 Adding comments to a test

You can either select from a list of standard comments or add a comment of your choice.

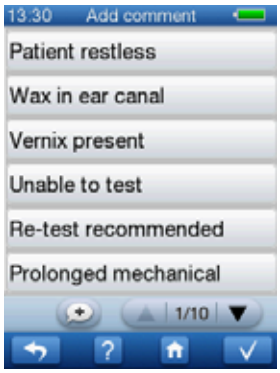
You can edit the predefined comments from AccuLink and then download them to AccuScreen.

5.3.1 Adding a standard comment

1. To add a standard comment, press the **Add Comments** button in the **Test Result** screen.

   This will take you to the **Comments** screen. If comments have already been added to a test, they are marked here.
2. In the **Comments** screen, you can select a predefined comment that may apply to this patient or the test conditions.

   Comments are configurable in AccuLink.

3. When you have selected a comment, press **OK** to save.

5.3.2 Adding a new comment

You can add comments from the individual test result screens and from the patient's **Test Menu**.

1. To add a new comment, press the **Add Comments** button in the **Comments** screen.

   This will take you to the **Add Comment** screen.

2. Enter one or several comments by using the data entry functions described below.
   See also 10.1.1 Using the keypad ▶ 77.
3. When you have entered a comment in the field, press the **OK** button to save.

5.3.3 Viewing comments

You can view comments from the individual test result screens and from the patient's **Test Menu**.

1. To view a comment, press the **View Comments** button.
   This will take you to the **Comment** screen. If comments have already been added to a test, they are listed here.

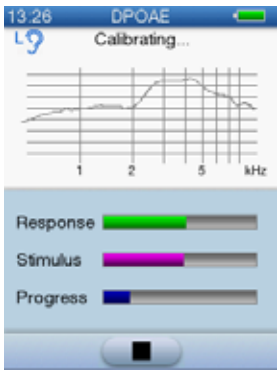
5.4 The DPOAE test

5.4.1 Starting the test

1. To start the test, press the **Start** button that is next to **DPOAE**, and that corresponds to the ear in which you placed the probe.

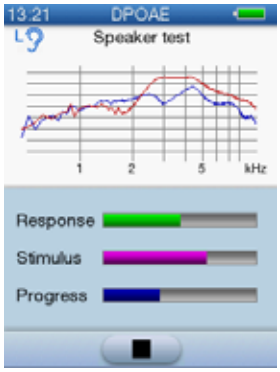
Calibration and speaker test are performed before the actual test starts.

The test starts automatically when calibration is completed.



Probe fit

If the probe does not fit correctly, adjust the position of the probe.



Speaker test

The probe fit is followed by a speaker test to make sure that the two speakers function correctly.

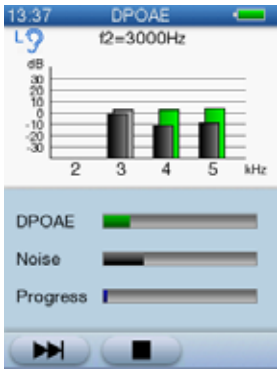
"Incomplete" message

If the message **Incomplete** appears:

- Refit the probe and make sure that it fits correctly.
- Press the **Start** button to restart the test.

5.4.2 The DPOAE test

The test as it progresses is shown on the display.

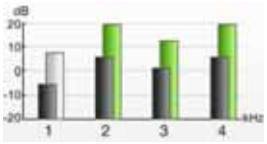


The frequency currently being tested is shown on the screen. See the bar chart legend below for a description of the columns.

- If needed, press the **Skip** button to skip a frequency.

The number of frequencies being tested is configurable. See the AccuLink User Manual.

- If needed, press the **Stop** button to stop the test. The test will be saved as an incomplete test.

Test details	
	Shows which ear is being tested.
Bar chart  Noise Registered DPOAE response: Frequency passed DPOAE frequency being tested, skipped or referred The height of the bars represents the noise/response amplitude. The test frequencies are shown below the bar chart. The test protocols are configurable (see the AccuLink User Manual). In a standard DPOAE test the 4 frequencies are • 5 kHz • 4 kHz • 3 kHz • 2 kHz where 5 kHz is tested first. The default PASS/REFER criterion is 3/4, which means that if 3 frequencies have reached a PASS, the entire test will PASS. The fourth remaining frequency will not be tested.	
	DPOAE Response at current test frequency.
	Noise Current noise level. Make sure the **Noise** level is as low as possible.
	Progress Shows the test progress. Max. time depends on environmental noise conditions. When the blue bar reaches the end, the test is completed.

Test duration - Regular DPOAE
Approximately 10 seconds on patients with normal hearing under quiet conditions, but highly dependent on test conditions in general.

5.4.3 DPOAE test results

When the test is completed, the test data is saved and the result is shown on the screen.

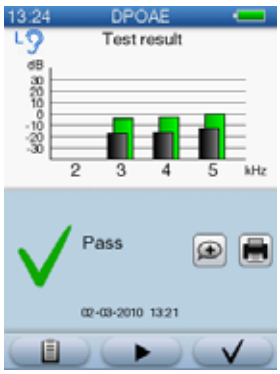
1. See 5.2.4 Options in the test result screens ▶ 42 for a description of the buttons available.
2. Press the **OK** button to return to the **Test Menu**.

The following PASS/REFER definitions apply only to the default DPOAE protocol for AccuScreen.

See the AccuLink User Manual for customized protocols.

PASS (Test passed)

For a standard DPOAE test, the complete test is terminated successfully with a *PASS (Test passed)* if DPOAEs could be registered for at least 3 frequencies.

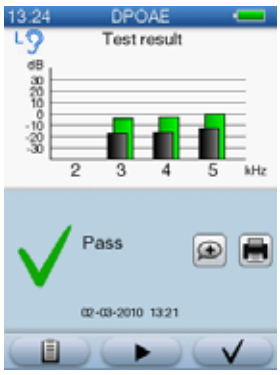


The results for AccuScreen are ordered and shown in decreasing frequencies, and depending on the setup.

5000 Hz
4000 Hz
3000 Hz
2000 Hz

Only **L2** is shown. The L1/L2 pair is 59/50 dB SPL.

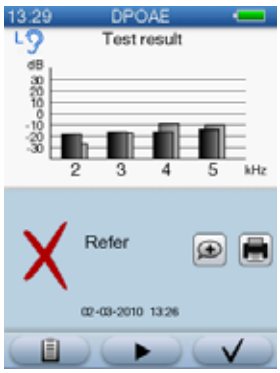
A *PASS (Test passed)* result indicates that the patient has normal outer hair cell function in at least 3 out of 4 different frequency regions of the cochlea at the time of testing.



A single frequency *PASS (Test passed)* is determined by a statistical algorithm based on weighted averaging, which ensures high-sensitivity detection.

REFER (Test referred)

If the result is a *REFER (Test referred)*, the detailed results are shown immediately below the graph.



A *REFER (Test referred)* result indicates that in at least 2 frequency bands out of 4, no significant DPOAE response could be detected.

Note · *Retro-cochlear hearing loss cannot be detected by DPOAE testing.*

The DPOAE result specifies each frequency tested. This facilitates decisions concerning further procedures. A *PASS (Test passed)* at a single frequency indicates near to normal hearing in the specified band.

The major reasons for non-detection are too noisy test conditions or a poor probe fit. In DPOAEs this is especially true for the lowest frequencies. Therefore, low frequency *REFER (Test referred)* with high frequency *PASS (Test passed)* is a strong indicator that test conditions were not optimal. If this is the case, it is recommended that you improve test conditions and repeat the test.

Incomplete test

If the test was stopped, an error message is shown.

The result screen appears differently from the one shown, if the test failed or was aborted during calibration.

5.5 The ABR test

The ABR tests are identical, except for the dB level at which the tests are performed. The level is indicated by the name of the tests: **ABR 35**, **ABR 40**, and **ABR 45**.

Caution · *Mobile phones, electrically controlled tables or desks and other such devices may issue noise that can influence ABR measurements and lead to false referrals. Make sure that you carry out testing away from such sources of noise.*

5.5.1 Starting the test

1. Place the electrodes on the patient to ensure that they have time to connect well to the skin, for instance while you explain the test process to relatives.
2. Connect the electrode cable.
3. Fit the probe or the ear couplers with the ear coupler cable. The ABR display changes automatically.
4. Decide on which ear you wish to perform the test, and prepare the patient as described in 4 Preparing for testing ▶ 29.

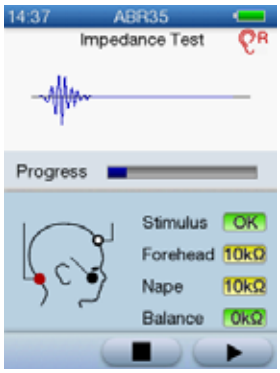
Testing one ear

- To start the test, press the **Start** button that is next to the **ABR** test, and that corresponds to the ear in which you placed the probe.

Testing both ears

- If you are testing with ear couplers, the **Binaural** button is shown.
  Press this button to test both ears.

5.5.2 Impedance testing and calibration

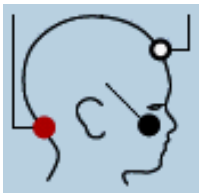


Electrode impedance testing followed by calibration are performed before the actual test starts.

All three impedance and balance indicators should prefereably be green (see Impedance test indicators ▶ 51), but the test can be started even if the indicators are yellow.

The **Start** button is greyed out until **Stimulus** and **Impedance** values are okay.

1. Press the **Start** button to start the test.

Impedance test indicators	
	Stimulus The acoustical stimulus is being calibrated.
	If the **Impedance** and **Balance** values are **OK** (green), press the **Start** button to start the test.
	
	Red (nape) The **Red** reading indicates the sum of the **Red** and the **Black** (reference) electrodes' skin impedances.
	White (high on the forehead) The **White** reading indicates the sum of the **White** and the **Black** (reference) electrodes' skin impedances.
Color coding	

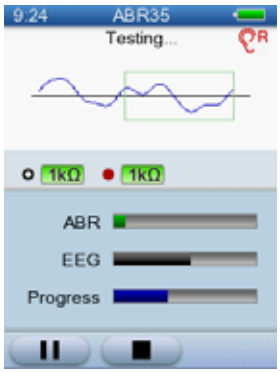
Impedance test indicators		
	• *Green*	Less than 4 kΩ: Good
	• *Yellow*	4 to 12 kΩ: Fair
	• *Red*	Poor More than 12 kΩ. Testing is not possible; the **Start** button is disabled; only **Stop** can be pressed.
	Balance Indicates the difference in the skin impedance of the white and the red electrode. This value should also be fairly low (less than 4 kΩ):	
	• *Green*	Good 0 to 2 kΩ
	• *Yellow*	Fair 2 to 4 kΩ
	• *Red*	Poor More than 4 kΩ. Testing is not possible; the **Start** button is disabled; only **Stop** can be pressed.

If impedance values are high

1. Make sure that the electrode cable is connected to AccuScreen.
2. Make sure that the electrodes are positioned correctly.
3. Make sure that the skin locations are clean.
   Use water and a soft cloth to clean skin locations for all three electrodes well before testing.
4. If needed, attach new electrodes to see whether they will reduce the impedance values.

5.5.3 The ABR test

The test as it progresses is shown on the display.



Pausing a test

- If required, press the **Pause** button to suspend the test, for instance if the test progresses well but is suddenly influenced by noise or movements.

  The **Pause** button changes into a **Start** button.

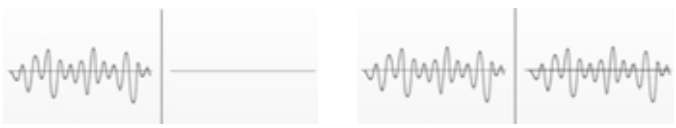
  Pressing the **Pause** button will store data registered up to this point in time. This will prevent registered data from being influenced by noise or movements.

  The test can be paused for max. 2 minutes each time you pause it.

- Press the **Start** button to resume the test.

Stopping a test

- If needed, press the **Stop** button to stop the test. The test will be saved as an incomplete test.

Test details	
	Shows which ear is being tested.
Single ear testing	
Binaural testing 	
	ABR Shows the ABR response.

Test details	
	EEG Is an indication of the amplitude of the total registered potential. The lower this value is, the easier the test will be. If the electrode signals are significantly high (disturbances, muscular artifacts) the data measured during this time will be ignored.
	Impedance These impedance values are updated and shown every 20 seconds. The actual test is like a race between Progress and ABR: • If **Progress** wins, the result is a *REFER (Test referred)*. • If **ABR** wins, the result is a *PASS (Test passed)*.
	Progress Shows the test progress. Max. time depends on environmental noise conditions.
	Pause Press to pause the test.

Test duration for babies

Single ear testing:
Approximately 1½ minutes on babies with normal hearing under quiet conditions, but highly dependent on test conditions in general.

Binaural testing:
Approximately 3 minutes on babies with normal hearing under quiet conditions, but highly dependent on test conditions in general.

5.5.4 ABR test results

When the test is completed, the test data is saved and the result is shown on the screen.

1. See 5.2.4 Options in the test result screens ▶ 42 for a description of the buttons available.
2. Press the **OK** button to return to the **Test Menu**.

Test result PASS (Test passed)

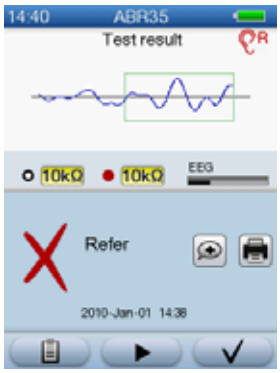
If the result is a *PASS (Test passed)*, only the graph is shown.

- A *PASS (Test passed)* indicates that an auditory brainstem response to a 35, 40 or 45 dB nHL broadband stimulus was detected.

  This method mainly tests the frequencies from 2 to 4 kHz, which carry the most important acoustic information for speech development.
- A *PASS (Test passed)* result ensures that a significant hearing loss in these frequencies can be ruled out with 99.5% confidence.

Test result REFER (Test referred)

If the result is a *REFER (Test referred)*, the detailed results are shown immediately below the graph.



- A *REFER (Test referred)* may indicate a significant hearing loss.
- A *REFER (Test referred)* may also be the result when too much electrical noise drowns out the response.

If the infant moves or is sucking or crying during the test, this may result in too much electrical noise. Other electrical appliances and fluorescent lighting in the vicinity can also cause electrical interference.

A good indication of this is if the ABR bar on the display is close to the *PASS (Test passed)* criterion but does not result in a *PASS*. If this is the case, try to improve test conditions and repeat the test.

Consequently, before you refer the patient for further follow-up, it is recommended that you improve test conditions and repeat the test:

- Does the probe fit well in the ear canal?
- Are the electrodes placed correctly and fit properly? Even if the device accepts the impedance values, it is often worth while to attempt to reduce impedance values and particularly the impedance differences. The noise in the electrode cable depends strongly on the impedance values.

- Is the patient well at rest and is there no muscle tension? Note that electric muscle artifacts may arise from non-moving but tensed muscles (isometric contraction). Please check especially the nape of the neck for this condition.
- Are there any sources of electric noise in the environment? Especially motor-driven devices such as pumps can cause high noise which is sometimes accepted by the device but can be too high, if for instance the response has a low amplitude. It may be worth while to relocate to another room for testing.
- Is there much acoustic noise in the environment? A high level of noise might mask the stimulus.

Incomplete test

If the test was stopped, an error message is shown.

5.6 Test view

A patient screened by AccuScreen is either given a *PASS (Test passed)* or a *REFER (Test referred)*.

- If the result is a *PASS (Test passed)*, no further action is required.
- If the result is a *REFER (Test referred)*, it is recommended that you retest the patient. If the patient is given yet another *REFER (Test referred)*, this patient should be referred for further testing.

5.6.1 Test View

You can view a patient's tests:

- from the **Home** screen
- from the **Patient Details** screen

From the Home screen

1. On the **Home** screen, press the **Test View** button.
   This will take you to a patient list for selecting a patient.
2. Select a patient. This will take you to the patient's **Test View** screen.

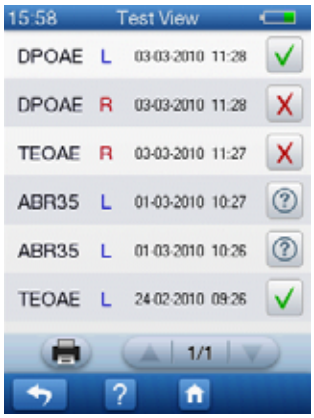
From the Patient Details screen

1. If needed, use the functions described in 3.2.2 Finding a patient ▶ 26 to find a patient.
2. Press the button showing the name of the patient you wish to select.
3. On the **Patient Details** screen, press the **Test View** button.

   This will take you to the patient's **Test View** screen.

5.6.2 The Test View screen

The **Test View** screen shows the tests that have been made on a particular patient.



The tests are listed according to date, with the most recent tests at the top of the list.

1. To view more tests, if available, press the arrow buttons to scroll up or down in the list.
   The **Test View** screen shows you information about
   - The type of tests that were made.
   - On which ear the test was made.
   - The date and time on which the test was made.

The test results

- **PASS (Test passed)**

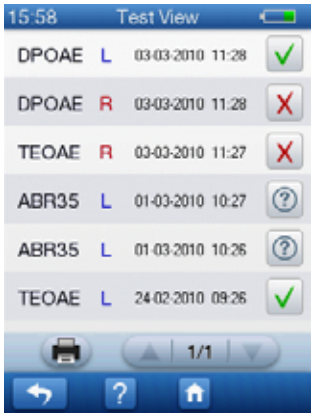
- **REFER (Test referred)**

- **Incomplete**

2. To view or print the individual test results, press the result icon. This will take you to a test result screen displaying the test you wish to view or print.

   For a description of the individual test result types, see:

   – 5.2.3 TEOAE test results ▶ 40
   – 5.4.3 DPOAE test results ▶ 48
   – 5.5.4 ABR test results ▶ 54



3. If you wish to view comments to a test result, press the **Comments** button in the specific test results screen.

6 Quick Test

With **Quick Test** you can perform a quick test in all test functions without having to assign the test to a specific patient. It is useful for demonstration or test purposes.

Note · *These test results are not stored. As a consequence, no data is available in the modes* **Test View** *and* **Print**.

6.1 Performing a Quick Test

1. Do as described in 4 Preparing for testing ▶ 29, but without adding a new patient or assigning the test to a specific patient.
2. Press the **Quick Test** button on the **Home** screen.

   From the **Quick Test** screen you can access the test types available in AccuScreen.

3. Prepare the patient as described in 4 Preparing for testing ▶ 29.

4. Press the **Start** button that is next to the test you wish to perform and that corresponds to the ear you have selected to test.

   - 5.2 The TEOAE test ▶ 38
   - 5.4 The DPOAE test ▶ 45
   - 5.5 The ABR test ▶ 50

Note · *These test results are not stored.*

See 5 Tests ▶ 37 for a the description of the individual tests.

7 Printing

You can print complete results from AccuScreen directly on a label printer (see 7.1 Printing from AccuScreen ▶ 61).
You can also print AccuScreen results from a PC with the AccuLink software if a printer is connected (see the AccuLink User Manual).

7.1 Printing from AccuScreen

Warning · *Before you make any printouts, make sure that the patient is not in contact with AccuScreen by removing the probe or ear couplers from the patient's ear and detaching all electrodes.*

Note · *Testing is not possible when AccuScreen is placed in the docking station.*

Note · *Do not switch off AccuScreen while printing is in progress. Doing so may result in distorted test data.*

Note · *If the label printer is not connected or if it is switched off, an error message appears on the screen.*

1. Connect the label printer cable to the AccuScreen docking station and place AccuScreen in the docking station.
2. Disconnect the docking station from the PC by removing the USB cable.

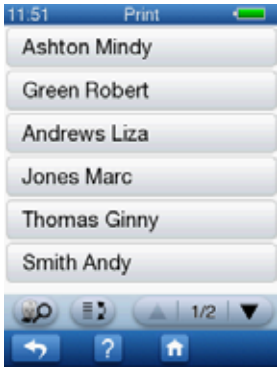
Note · *Use only the label printer recommended. AccuScreen automatically recognizes the label printer.*

3. Switch on the printer.

Selecting the patient

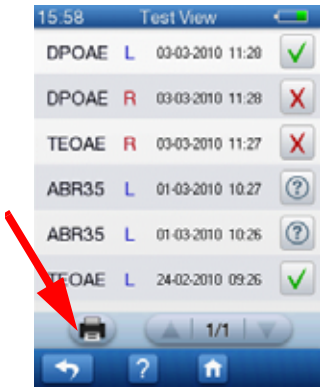
1. Switch on AccuScreen and press the **Print** button on the **Home** screen.
   This will take you to the **Test History/Print** patient list.

2. Press the button showing the name of the patient you wish to select. If needed, see 3.2.2 Finding a patient ▶ 26.
   This will take you to the **Test View** screen.

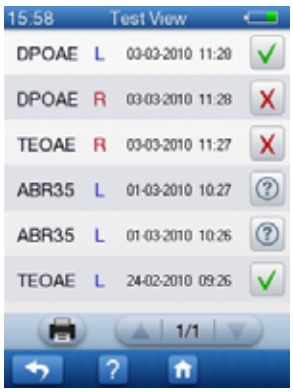


Printing

1. To print the entire list from the **Test View** screen, press the **Print** button on this screen.
   Patient specific comments will be printed automatically.



2. To access a test result, press the row displaying the test you wish to print.



3. Press the **Print** button in the specific **Test Result** screen.

   Test specific comments will be printed automatically.

7.2 Printouts from label printer

The printouts show:

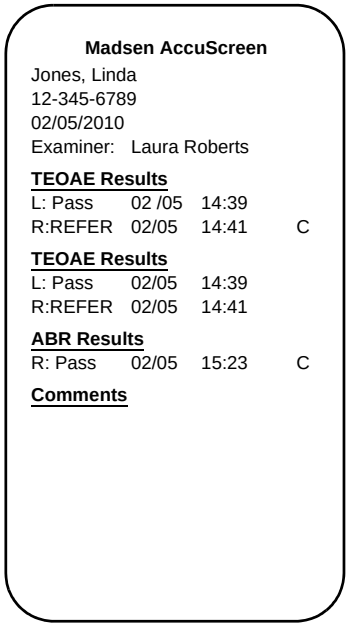
- The patient's first and last name
- Patient ID
- Date of testing
- Examiner's name
- Test type
- Left and/or right ear result, date and time
- General comments relating to the patient are listed at the bottom of the printout

All results

The most recent and best results of all tests on this patient are combined in one printout:

- TEOAE results
- DPOAE results
- ABR results

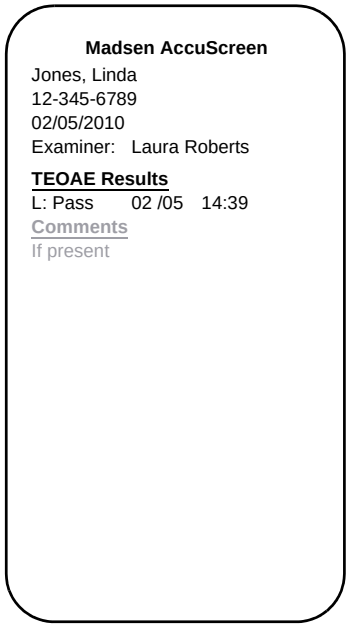
If there are no results for a specific type of test, the test type is not listed.



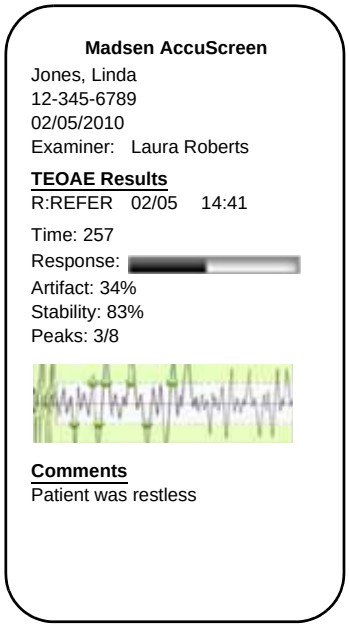
Single results

The most recent result is printed.

PASS



REFER



Legend

Legend	
L **R**	• Left ear • Right ear
C	• There are comments relating to a specific test. To view these comments a print of the single result is needed.

Printouts from label printer

8 Quality Tests

From the **Quality Tests** menu you can test the probe and cables connected to AccuScreen.

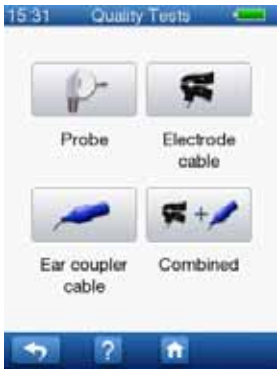
We recommend that you test the probe and cables at the beginning of each work day.

Note · *You should always comply with local regulations and routines.*

8.1 Performing Quality Tests

1. Press the **Quality Tests** button on the **Home** screen.

2. From the **Quality Tests** menu you can access the quality test types available in AccuScreen:



- **Probe**
  8.2 Probe test ▶ 67
- **Electrode cable**
  8.3 Electrode cable test ▶ 69
- **Ear coupler cable**
  8.4 Ear coupler cable test ▶ 70
- **Combined** (Electrode cable - Ear coupler cable)
  8.5 Combined (Electrode Cable - Ear Coupler Cable) ▶ 71

8.2 Probe test

Every day before you start testing on patients, you should test the probe to make sure that it functions correctly.

Caution · *Make sure that the probe tip has been cleaned and disinfected before you insert it in the test cavity. See 11.4.1 Cleaning and disinfecting the test cavity ▶ 85.*

You can start the probe test in two ways:

- 8.2.2 Performing the Probe Test ▶ 68, simply by inserting the probe in the test cavity of AccuScreen.
- 8.2.1 From the Quality Tests menu ▶ 68

8.2.1 From the Quality Tests menu

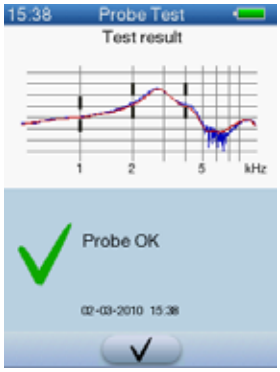
1. Press the **Probe** button on the **Quality Tests** screen.
2. Follow the instructions in 8.2.2 Performing the Probe Test ▶ 68.

8.2.2 Performing the Probe Test

1. Insert the probe tip without eartip in the test cavity.
   The test starts automatically.

Note · *The Probe Test does not start automatically e.g., when a patient is being created.*

If the probe functions correctly, the message **Probe OK** appears.



If the probe does not function correctly, the message **Probe Test failed!** appears.
You will also see a list of possible errors.

2. If needed, press the **Start** button to repeat the test.

3. Press the **OK** button to confirm the test result.

8.3 Electrode cable test

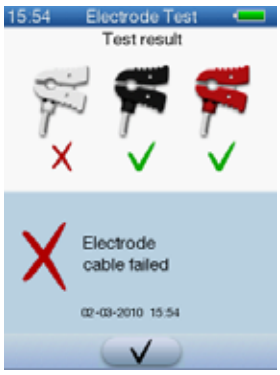
Every day before you start testing on patients, you should test the electrode cable to make sure that it functions correctly.

1. Clip the electrode clips onto the metal bars of the ABR Tester.
2. Press the **Electrode cable** button on the **Quality Tests** screen.

3. Press the **Start** button to start the test.

If the electrode cables function correctly, the message **Electrode cable OK** appears.

If one or more of the electrode cables do not function correctly, the message **Electrode cable failed** appears.



4. If needed, press the **Start** button to repeat the test.

5. Press the **OK** button to confirm the test result.

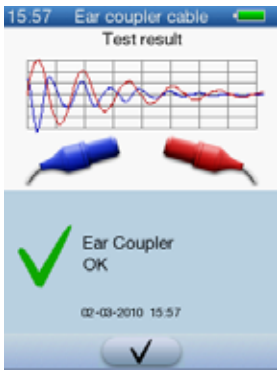
8.4 Ear coupler cable test

Every day before you start testing on patients, you should test the ear coupler cable to make sure that it functions correctly.

1. Insert the transducers into the socket at each end of the ABR Tester.
2. Press the **Ear coupler cable** button on the **Quality Tests** screen.

3. Press the **Start** button to start the test.

If the ear coupler cables function correctly, the message **Ear Coupler OK** appears.



Caution · *To remove the ear coupler cables, do not pull them by the cable. Instead, hold them by the transducer.*

If one or both ear coupler cables do not function correctly, the message **Ear Coupler failed** appears.

4. If needed, press the **Start** button to repeat the test.

5. Press the **OK** button to confirm the test result.

8.5 Combined (Electrode Cable - Ear Coupler Cable)

Every day before you start testing on patients, you can test the electrode cable and ear coupler cables combined to make sure that they function correctly.

1. Clip the electrode clips onto the metal bars of the ABR Tester.
2. Insert the transducers into the socket at each end of the ABR Tester.

3. Press the **Combined** button on the **Quality Tests** screen.

4. Press the **Start** button to start the test.

If the electrode cables and ear coupler cables function correctly, the message **All tests OK** appears.

If one or several electrode cables and/or ear coupler cables do not function correctly, the message **Test FAILED** appears.

5. If needed, press the **Start** button to repeat the test.

6. Press the **OK** button to confirm the test result.

Caution · *To remove the ear coupler cables, do not pull them by the cable. Instead, hold them by the transducer.*

9 AccuScreen settings

You can configure your AccuScreen from the AccuScreen **Settings** menu and from AccuLink.

AccuScreen
From the AccuScreen **Settings** menu you can:

- change time and date settings
- change the language setting
- change the sound settings
- change the brightness of the display
- view system information

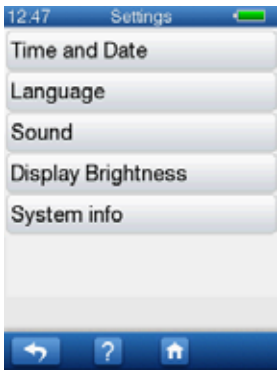
AccuLink
Settings which can be configured from AccuLink are described in the AccuLink User Manual.

9.1 The Settings menu

From the **Settings** menu, you can change the basic settings of AccuScreen, and see information about the hardware and the software installed.

1. Press the **Settings** button on the **Home** screen.

   From the **Settings** menu you can access the settings available in AccuScreen.



9.2 Time and Date setting

1. Press the **Time and Date** button on the **Settings** screen.
   You can set the date in the upper part of the screen and the time in the lower part.

Note · *If you leave the* **Time and Date** *screen by pressing the* **OK** *button, the setting of seconds is set to zero.*

2. Press the arrows to select the day (DD), month (MM), year (YYYY), hours (HH) and minutes (MIN).

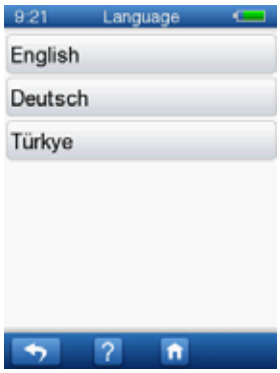
3. Press the **Tool** button to change the date and time formats.

   – **Date**
   Select from the list how the date setting is to be shown on the screen.

   – **Time**
   Select from the list how the time setting is to be shown on the screen.

9.3 Language setting

1. Press the **Language** button on the **Settings** screen.
2. To change the language on AccuScreen, press the button with the preferred language.

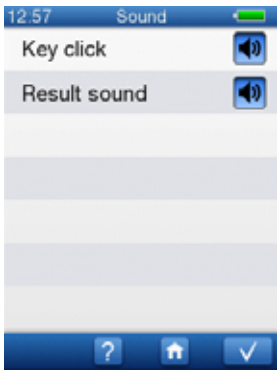


Note · *Your screen showing the available languages may not appear as the one shown.*

9.4 Sound setting

1. Press the **Sound** button on the **Settings** screen.

   You can switch sounds on/off for button strokes and test results by pressing the relevant button.



Sound on

- **Key click**
  Pressing a button will produce a sound (a click)
- **Result sound**
  A *PASS* or *REFER* sound is heard at the end of the test.

Sound off

Shows that the sound is disabled.

9.5 Display Brightness

1. Press the **Display** button on the **Settings** screen.

   To change the brightness of the display, press the buttons on either side of the green bar.

Note · *A high level of brightness will influence the power consumption of the device.*

   – Darkens the display

   – Brightens the display

   – Press the Default button to use the default setting for the display brightness.

9.6 System Info

1. Press the **System Info** button on the **Settings** screen to view information regarding:
   – Firmware release
   – Release date
   – HW version and Serial number
   – Connected probe
   – Next service date
   – Memory usage

10 Handling Data in AccuScreen

10.1 Entering data in AccuScreen

10.1.1 Using the keypad

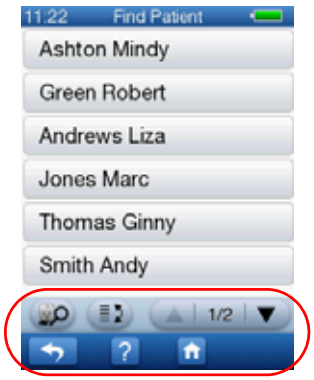
To enter or edit data, select the characters and/or digits from the keypad.

Data entry functions	
• To enter an upper case character, press the **Shift** arrow. When you have entered one character, the keypad reverts to lower case characters. The first character in a field will always be upper case. • *Press twice* to write only upper case character. • *Press once* to return to lower case character.	
Special characters button • Select to enter special characters (when the keypad is displaying standard characters). • Select to enter standard characters (when the keypad is displaying special characters).	
Digits and symbols button • Select to enter digits or symbols (when the keypad is displaying standard characters,). • Select to enter standard characters (when the keypad is displaying special digits and symbols).	
• **Space** Select to insert a space.	
• Press to move the cursor left or right within the field.	

Data entry functions	
• When you have entered the data, press the **OK** button to confirm. This will take you to the next mandatory field.	

10.2 Function buttons

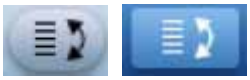
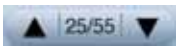
In AccuScreen you can perform a number of functions, such as finding patients, viewing patients' test histories, scrolling in lists, etc.



Available functions are shown in the function bar of the AccuScreen screens.

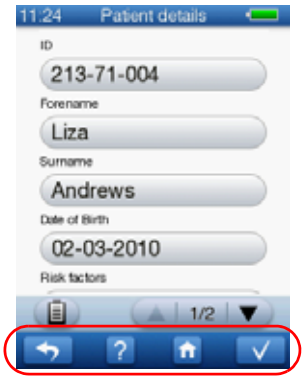
These functions vary from screen to screen.

- To perform these functions, simply press the relevant function button.

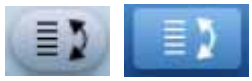
Function buttons	
• **Patient search** – Press the button – Enter the patient's name – Press the **OK** button to start the search.	
• **Change search criteria** – Press the button. If needed, do so repeatedly until you see the category you wish to use. The category is shown as greyed out text at the top of the screen.	
• Scroll to see more/next page/next patients in list	 
• Test view – Press the button to see the patient's test list.	

10.3 General buttons

Available main functions are shown in the footer bar of the AccuScreen screens.



- To perform these functions, simply press the relevant button.

General buttons	
• Return to previous screen	
• Help	
• Go to the Home screen	
• OK/Confirm/Save/Go to next field/Go to next screen	
• Toggle search criteria	

10.4 Deleting data

If needed, the system administrator can set up AccuScreen to automatically delete data after data transfer to AccuLink. See the AccuLink User Manual.

10.4.1 Deleting one patient

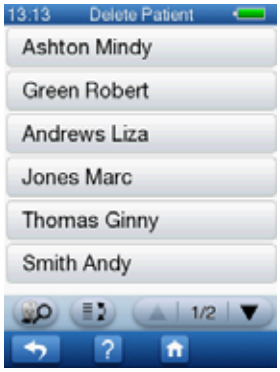
1. To delete one single patient, press the **Delete** button on the **Home** screen.

This will take you directly to the **Delete** menu to select the patients you wish to delete.

2. Press the **Single Patient** button.

This takes you to the **Delete Patient** screen to select the name of the patient you wish to delete from the list.

3. Press the button showing the name of the patient you wish to delete, or search for a patient as described in 3.2.2 Finding a patient ▶ 26.



You will be prompted to confirm that you wish to delete this patient.

All test results relating to this patient will be deleted.

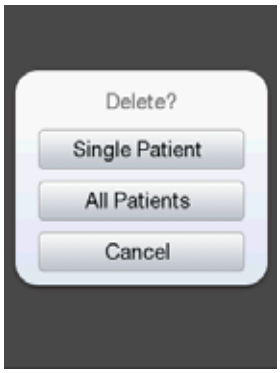
4. Press the **Home** button to go to the **Home** screen.

10.4.2 Deleting all patients

1. To delete all patients, press the **Delete** button on the **Home** screen.

This will take you directly to the **Delete** menu.

2. Press the **All Patients** button.



You will be prompted to confirm that you wish to delete all patients. All test results relating to all patients will be deleted.

3. Press the **Home** button to go to the **Home** screen.

11 Maintenance and Cleaning

11.1 The probe tip and probe body

Probe tips are disposable and should not be cleaned.

Note · *Probe tips should be disposed of according to local regulations.*

Warning · *Never place the probe tip in the ear canal without using a clean eartip.*

The probe tip usually does not come into contact with the skin or secretion from the ear canal, as it is covered by the eartip, but you should check the channels in the probe tip every time you have used the probe. Even small amounts of cerumen or vernix can block the probe channels or be deposited on the probe tip.

Warning · *If needed, replace the probe tip with a spare one.*

11.1.1 Regular cleaning

Caution · *You should always comply with local hygienic standards.*

The probe tip

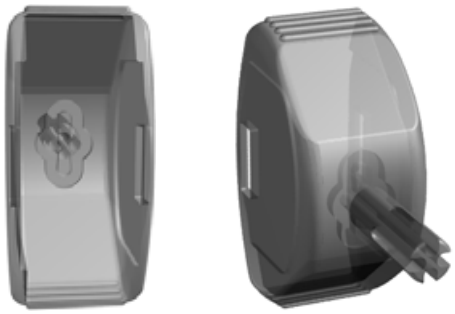
– Remove the probe tip from the probe.

– Use the cleaning wire to clean the sound channels of the probe tip from the rear.

Note · *Remember to clean the cleaning wire when it protrudes from the probe tip.*

When you have finished using the cleaning wire, remember to disinfect it.

– Make sure that the sound channels are completely dry before you fit the tip back onto the probe body. If needed, use a spare probe tip.



The probe body

Important · *For periodical cleaning of the probe body, contact your authorized service department.*

Caution · *The probe body contains sensitive components. Never clean the sound apertures in the probe body mechanically or with liquids. Doing so may cause damage to the probe.*

Caution · *Even the slightest amount of moisture may dissolve any residual cerumen and contaminate the sensitive parts in the body of the probe.*

– Use a wet tissue with alcohol for regular surface cleaning.

11.1.2 Probe calibration

The AccuScreen probe is calibrated at the factory prior to delivery. This is why there may not be a full year to the next calibration date, as stated on the calibration certificate, when you receive AccuScreen.

The first time you connect the probe to AccuScreen and perform a test, the calibration date will be set so that there is one year to the next calibration.

To view the next calibration date, select **Settings > System info**. Before you perform the first test, the date field will be blank.

Calibration frequency
The probe should be calibrated annually by factory authorized service personnel.

11.2 Eartips

Eartips are disposable and should not be cleaned.

Note · *Eartips should be disposed of according to local regulations.*

11.3 Cleaning the ear coupler cable

Always mount the ear couplers on the ear coupler adapters before use to prevent the ear coupler adapters from coming into contact with the patient. The ear couplers are disposable items and should be used only on one patient.

If there is a risk of cross-infection, clean the adapters. Otherwise, clean the adapters at the end of the day:

1. Disconnect the ear coupler cable from AccuScreen.

Caution · *Never immerse the ear coupler cable in liquid.*

2. Use a wet tissue with alcohol to clean the ear coupler cable and the ear coupler adapter. Wipe only with disinfectants and make sure that liquid does not enter the ear coupler adapter.

11.4 Cleaning AccuScreen

- Before cleaning, switch off AccuScreen and unplug it from any external power source.
- Unplug the probe from AccuScreen.

Caution · *Use only wiping disinfectant.*

Caution · *Always make sure that no moisture enters the probe, the sockets (data interface connector and probe plugs) or the test cavity.*

Caution · *Never immerse AccuScreen into water or other cleaning solutions.*

- Clean AccuScreen with a moist cloth - if required, use a little surface disinfectant.

11.4.1 Cleaning and disinfecting the test cavity

If needed, use a wet tissue with alcohol to clean the entry surface of the test cavity.

Caution · *Make sure that no liquid enters the test cavity.*

If the test cavity has been contaminated with debris from the probe tip, make sure that the test cavity cannot be used, for instance by sticking a piece of tape across the entry hole, and contact your authorized service department for cleaning and/or replacement of the test cavity.

11.5 Battery safety and maintenance

11.5.1 Safety information

Explosion hazard

Warning · *Keep the battery away from heat or open fire, and do not throw it into fire, as this may cause the battery to explode.*

Warning · *The battery used in this device may present a risk of fire or chemical burn if mistreated. Do no disassemble, heat above 60°C (140°F) or incinerate.*

- Incorrect handling, applying excessive charging current or reversing the poles can overcharge or destroy the battery.
- Do not open, alter or dismantle the battery.
- Do not place the battery in contact with metal objects.
- The terminals must under no circumstances be short-circuited.

11.5.2 Increasing service life

- Use only the battery type, docking station and charger stated in App. 3.4 Power supply and battery ▶ 104 and App. 3.5 1077 docking station (optional accessory) ▶ 104.
- Charge the battery at room temperature whenever possible.
- Do not drop the battery or expose it to sharp impact.
- Store in a cool, dry place.
- Keep the battery's terminals clean. Clean with a soft cloth if necessary.

Battery renewal

The battery capacity will gradually degrade by many charging/discharging cycles and by ageing. We recommend that you fit the instrument with a new battery approximately every 12 to 18 months.

The need for renewing the battery depends on the usage pattern and the battery capacity needed.

11.5.3 Disposal of old batteries

Note · *Li-Ion batteries can be recycled!*

Caution · *Dispose of used battery promptly.*

Caution · *Keep away from children.*

Caution · *Do not disassemble and do not dispose of in fire.*

Environmental protection

- When the Li-Ion battery loses its capacity to be charged, make sure that it is disposed of according to local environmental regulations, or return it to your dealer.

App. 1 Standards and Safety

This manual contains information and warnings that must be followed to ensure safe performance of AccuScreen. Local government rules and regulations, if applicable, should be followed at all times.

App. 1.1 AccuScreen symbols

Symbol	Definition
	Warning · *The instrument is marked with this symbol when it is important that the user refers to associated warnings given in this manual. Please pay special attention to these warnings.*
	The instrument is marked with this symbol to indicate compliance with Type BF requirements of EN60601-1. This class of equipment is allowed in domestic establishments when used under the jurisdiction of a health care professional.
	Classified with respect to electrical shock, fire, mechanical and other specified hazards only in accordance with UL60601-1 and CAN/CSA-C22.2 NO 601.1-90.
	The instrument and this manual are CE-marked according to the Medical Devices Directive 93/42/EEC.

Symbol	Definition
	The instrument is marked with this symbol to indicate that it is electronic equipment covered by the Directive 2002/96/EC on waste electrical and electronic equipment (WEEE). In European countries the crossed-out wheeled-bin WEEE symbol reminds you that all the electrical and electronic products, batteries, and accumulators must be taken to separate collection at the end of their working life. This requirement applies in the European Union. Do not dispose of these products as unsorted municipal waste. You can return your instrument and accessories to Otometrics, or to any Otometrics supplier. You can also contact your local authorities for advice on disposal.

App. 1.2 Docking station symbols

Symbol	Definition
	Warning · *The docking station is marked with this symbol when it is important that the user refers to associated warnings given in this manual. Please pay special attention to these warnings.*
	The docking station is marked with this symbol to indicate that it is suitable for direct current only.
	The docking station and this manual are CE-marked according to the Medical Devices Directive 93/42/EEC.
	The docking station is marked with this symbol to indicate that it is electronic equipment covered by the Directive 2002/96/EC on waste electrical and electronic equipment (WEEE). In European countries the crossed-out wheeled-bin WEEE symbol reminds you that all the electrical and electronic products, batteries, and accumulators must be taken to separate collection at the end of their working life. This requirement applies in the European Union. Do not dispose of these products as unsorted municipal waste. You can return your instrument and accessories to Otometrics, or to any Otometrics supplier. You can also contact your local authorities for advice on disposal.

App. 1.3 Warning notes - AccuScreen

Warning · *The following conditions or practices might present possible injury or danger to the patient and/or the user:*

- Do not connect any external device (e.g., printer) to AccuScreen during testing.
- If AccuScreen is used during surgery, the probe and connectors must not touch conductive items including ground.
- The probe socket is intended to connect the ear probe to AccuScreen. No other device may be connected to this socket.
- AccuScreen must not be used during the application of:
  - HF surgical devices,
  - cardiac pacemakers
  - defibrillators
  - other electrical stimulators
- AccuScreen must not be used during the application of HF surgical devices as this may result in burns at the site of the electrical stimulator of the biopotential input part electrodes and possible damage to the electrical stimulator or biological amplifiers.
- Conductive parts of electrodes and their connectors including the neutral electrode are not to contact other conductive parts and earth.
- Avoid accidental contact between connected but unused applied parts and other conductive parts including those connected to protective earth.
- Do not store or operate AccuScreen at temperatures and humidity exceeding those stated in Technical Specifications, App. 3.3.15 Operating environment ▶ 103.
- Do not use the instrument in the presence of flammable anesthetics (gases).
- No parts may be eaten, burnt, or in any other way used for purposes other than audiometry.
- We recommend that an annual calibration be performed on AccuScreen and probe. Furthermore, we recommend that calibration be performed if the equipment has suffered any potential damage.
- For safety reasons, accessories connected to the equipment's outlet sockets must be supplied with the system.
- Disposable accessories, such as eartips, should not be reused and must be replaced between patients to prevent cross-infection.
- This class of equipment is allowed in domestic establishments when used under the jurisdiction of a health care professional.
- Unwanted noise may occur if AccuScreen is exposed to a strong radio field, and such noise may interfere in the process of testing. Many types of electrical devices, e.g. mobile telephones, may generate radio fields. We recommend that the use of such devices in the vicinity of AccuScreen be restricted.

- AccuScreen's RF emissions are very low and are not likely to cause any interference in nearby electronic equipment, but negative effect or loss of functionality of other local devices may occour if, they are placed in close vicinity of AccuScreen.
- Make sure that the PC with the AccuLink software and the docking station is not within patient reach.

- When assembling an electro-medical system, the person carrying out the assembly must take into account that other connected equipment which does not comply with the same safety requirements as this product may lead to a reduction in the overall safety level of the system.

App. 1.4 Warning notes - docking station

- Use only the power supplies specified in Technical Specifications, App. 3.5.4 Power adapter ▶ 105.

App. 1.5 Warranty

AccuScreen is guaranteed against original defects in material and workmanship. It is also guaranteed to perform in accordance with the manufacturer's specifications for a full 2 years from the date of purchase.

The warranty does not apply to the battery, to wear parts and disposable items.

This warranty only applies to those instruments purchased from authorized distributors or representatives. The purchaser must return the instrument to an authorized distributor or representative and bear the cost of shipping.

This warranty does not cover breakage or failure due to tampering, misuse, neglect, accidents, modification or shipping and is void if the instrument is not used in accordance with the manufacturer's instructions.

Please return your instrument to your local distributor or representative for warranty attention!

Important · *The warranty will become void if the probe cleaning instructions are not strictly adhered to. If the probe is not cleaned regularly as directed in the instructions, cerumen may result in blockage of the probe, where sensitive components are contained and could be damaged.*

App. 1.6 Repair, after-sales service and regular checks

If AccuScreen as such is found to be defective or in some way varies from the manufacturer's specifications, an authorized dealer will repair, replace or re-calibrate the instrument at no cost to the purchaser while AccuScreen is within the warranty period.

Service and repair of electro-medical equipment should only be carried out by the equipment manufacturer or by authorized representatives.

The manufacturer reserves the right to disclaim all responsibility for the operation safety, reliability and performance of equipment serviced or repaired by other parties.

Following repair, a qualified electronics engineer should verify the safety of all equipment.

Calibration should be performed annually by suitably qualified personnel using the appropriate equipment.

App. 1.6.1 Declaration

All devices of the type AccuScreen should be checked and calibrated annually through a service center authorized by the manufacturer.

App. 1.7 Manufacturer

GN Otometrics A/S
9 Hoerskaetten
DK-2630 Taastrup
T: +45 45 75 55 55, **F**: +45 45 75 55 59
www.otometrics.com

App. 1.7.1 Responsibility of the manufacturer

Damage resulting from failure to observe the instructions for use will invalidate all warranty claims. The manufacturer takes no responsibility for damage resulting from negligence.

The manufacturer is to be considered responsible for the effects on safety, reliability, and performance of the equipment ONLY IF:

- All assembly operations, extensions, re-adjustments, modifications or repairs are carried out by personnel authorized by the manufacturer.

- The electrical installation to which the equipment is connected is grounded and complies with IEC requirements.
- The equipment is used in accordance with the instructions for use.

The manufacturer reserves the right to disclaim all responsibility for the operating safety, reliability and performance of equipment serviced or repaired by other parties.

App. 2 Status and Error Messages

App. 2.1 Device related messages

Error message	Cause	Solution
	• The battery charge is low.	• Recharge AccuScreen or replace the battery with a spare.
Low battery voltage	• The battery charge is low.	• Recharge AccuScreen or replace the battery with a spare.
The last device configuration was incomplete!	• The last configuration of AccuScreen may have been interrupted e.g. if the device was removed from the docking station during synchronisation.	• Place AccuScreen in the docking station and synchronize via the **Instrument Management** tool in the AccuLink software.
The real time clock data is invalid. Please set time and date.	• The real time clock power backup has been completely drained.	• Set the time and date: Select **Settings > Date and Time**, or synchronize the unit with AccuLink.
Hardware failure	•	• Contact your supplier.
Real time clock error	• Self test error.	• Contact your supplier.
Memory error	• Self test error.	• Contact your supplier.
FLASH runtime error	• Self test error: Invalid patient or test data has been found in flash memory.	• Try to upload data to AccuLink, delete all patient data and restart. If the message re-appears, contact your supplier.
Codec malfunction	• Self test error.	• Restart the device. If the message re-appears, contact your supplier.

App. 2.2 Usage and test related messages

Error message	Cause	Solution
Access is blocked for 24 hours. This user account is blocked because of too many unsuccessful log-in attempts.	• A wrong password has been entered 3 times. The device is locked for the user for 24 hours.	• The administrator can unlock the device via the AccuLink software.
The maximum number of patients is reached. Cannot generate new patient.	• There is no memory space available for adding more patients or tests.	• Delete patients and tests.
Wrong probe for test	• The TEOAE probe is connected for DPOAE testing or the Ear Coupler cable is connected for OAE testing.	• Connect the appropriate probe.
Probe FAILED	• The probe did not pass the test. There may be several causes: – the probe tip is blocked – the test cavity is blocked – the probe is damaged	• Make sure that the probe tip is clean and that the channels are not blocked. • Make sure that the test cavity is not blocked by e.g., dust, lint or such. • Replace the probe with a spare one and carry out the probe test to establish if the probe is damaged.
Speaker mismatch	• Too great a difference between speaker levels was detected.	• Clean the probe tip or replace with a spare and redo the test.
Too much noise	• Baby or testing environment is too noisy.	• Reduce noise (parents' talk, mobile phones, baby crying, etc.).
Stimulus high	• The probe has a poor fit in the ear canal. • The probe is not in the ear canal.	• Try to refit the probe.
Stimulus low	• The probe has a poor fit in the ear canal. • The probe tip is blocked.	• Try to refit the probe. If the problem persists, clean the probe tip or replace it with a spare.
Timeout during pause	• The ABR test was paused for more than 2 minutes.	• Retest the patient.

Error message	Cause	Solution
Paper feed error	• The labels are not adjusted correctly in the label printer or there is a paper jam.	• Re-adjust the labels and remove possible blocking of paper feed.

Usage and test related messages

App. 3 Technical Specifications

App. 3.1 Accessories[1]

App. 3.1.1 Standard accessories

Carrying case
Docking station, including power adapter and USB cable
Starter kit
OAE probe (DPOAE/TEOAE or TEOAE only)
Battery
ABR electrode cable (ABR version only)
ABR tester (ABR version only)
Cleaning cloth
User manual

App. 3.1.2 Optional accessories

Label printer with printer cable
ABR ear coupler cable
External battery charger

App. 3.2 Device

MADSEN AccuScreen is type 1077 from GN Otometrics A/S.

App. 3.3 Measurement techniques

App. 3.3.1 TEOAE

Sampling rate: 16 kHz

[1] Standard accessories and optional accessories may vary from country to country - please consult your local distributor.

Evaluation method:	Noise-weighted averaging, counting of significant signal peaks
Stimulus:	Non-linear click sequence
Stimulus level:	70-84 dB SPL (45-60 dB HL), self calibration depending on ear canal volume
Click rate:	Approx. 60 Hz
Frequency range:	1.5 to 4.5 kHz
Display:	Statistical waveform, measurement progress, TEOAE detection level, noise level

App. 3.3.2 DPOAE

Sampling rate:	24 kHz
Evaluation method:	Noise-weighted phase statistics
Stimulus:	Primary tone pair, f2/f1 = 1.24
Frame length:	512 samples
Available test frequencies:	Configurable, f2 range 1 to 6 kHz
Default test frequencies:	f2 = 2, 3, 4 and 5 kHz (PASS at 3 out of 4)
Test level:	l1/l2 = 59/50 dB SPL
Display:	DPOAE level, test progress, noise level, DP-Gram
Result display:	Overall PASS/REFER, DP-Gram with DPOAE and noise level

App. 3.3.3 ABR

Sampling rate:	16 kHz
Evaluation method:	Noise-weighted averaging and template matching
Stimulus:	35, 40 or 45 dB nHL click
Click rate:	Approx. 80 Hz
Amplifier gain:	2000
Amplifier CMRR:	> 100 dB @ 50 Hz

Input impedance:	10^{10} Ω || 50 pF
Input bias current:	< 10 nA
Input bandwidth:	70 Hz to 4 kHz
Impedance sense current:	Approx. 3.3 µApp
Impedance sense signal:	1 kHz square wave
Impedance test range:	1 to 99 kΩ
Impedance accepted for test:	< 12 kΩ
Impedance control:	Before test, periodically during test, stimulus continues during impedance control
Display:	Statistical graph, test progress, EEG-level, ABR detection probability
Electrodes:	Disposable hydrogel electrodes

App. 3.3.4 Dimensions

Approx.	202 x 73 x 30 mm (8 x 2.8 x 1.2 inches)

App. 3.3.5 Weight

Approx.	240 g (8.5 oz) excluding battery 280 g (9.9 oz) including battery

App. 3.3.6 Display

Type:	Color, TFT, touch screen
Dimensions:	89.4 mm (3.5 inches)
Resolution:	240 x 320 pixels
Backlight type:	LED, adjustable

App. 3.3.7 Keypad

Resistive touch screen (can be used with gloves)

App. 3.3.8 Sound

Built-in speaker for key click and PASS/REFER sounds

App. 3.3.9 Language settings

Up to 5 user selectable languages available in selected language package

App. 3.3.10 Memory

Patient memory capacity:	Max. 250 patients
Test memory capacity:	Min. 500 tests

App. 3.3.11 Connectors

OAE probe connector:	14 pin ODU Medisnap - For OAE Probe or ABR ear coupler cable
ABR (ABR version only):	4 pin ODU Medisnap - For ABR electrode cable

App. 3.3.12 Real time clock

Integrated real time clock for time-stamping of measurements. The clock is automatically synchronized with PC clock when docked.

Accuracy:	Max. deviation 12 minutes/year
Backup:	Min. 5 days, when battery is removed from unit

App. 3.3.13 Data interfaces

PC:	IR data transmission to docking station - USB interface from docking station to PC
Label printer:	IR data transmission to docking station - RS232 interface from docking station to label printer
Modem:	IR data transmission to docking station - RS232 interface from docking station to modem

App. 3.3.14 Transport and storage environment

Temperature range:	-20 - +60°C (-4 - 140 °F)
Humidity range:	20-80 % rel., non-condensing
Air pressure	500 hPa to 1060 hPa

App. 3.3.15 Operating environment

Mode of operation:	Continuous
Temperature range:	10 - 40°C (50 - 104°F)
Humidity range:	30-80 % rel., non-condensing
Air pressure	600 hPa to 1060 hPa

App. 3.3.16 Warm-up time

< 20 seconds.

Note · *Should be extended if MADSEN AccuScreen has been stored in a cold environment.*

App. 3.3.17 Disposal

MADSEN AccuScreen can be disposed of as normal electronic waste, according to WEEE and local regulations.

App. 3.3.18 Standards

Otoacoustic emissions:	EN 60645-6, Type 2
Auditory evoked potentials:	EN 60645-7, Type 2
Patient Safety:	• EN 60601-1, Internally Powered, Type BF, IPXO • U2601-1; CAN/CSA-C22.2 NO 601.1-90, • IEC 60601-2-26 • IEC 60601-2-40
EMC:	EN 60601-1-2

App. 3.4 Power supply and battery

Device

Supply voltage:	Nom. 3.70 V, Max. 4.20 V, Min. 3.20 V (measured with device load)
Maximum battery power consumption:	1.5 W while measuring
Estimated battery life:	8 hours of continuous use (based on a typical use scenario. Actual use can influence the battery life time.)
Battery level indicator:	5-step battery level indicator
Charge time in AccuScreen, in docking station:	80% charged: 4½ hours Fully charged: 6 hours

Battery

Caution · *Use only rechargeable battery supplied by GN Otometrics A/S, Part no. 8-73-02400. Use of any other battery may present a risk of fire or explosion.*

Battery type:	Rechargeable Li-ion 3.7 V/1800 mAh (6.7 Wh), fully charged

App. 3.5 1077 docking station (optional accessory)

App. 3.5.1 PC interface

Interface type:	USB 2.0, Full-speed
USB Power:	Uses <100 mA of current from the USB interface

App. 3.5.2 Printer/modem interface

Interface type:	RS232
Connector type:	6-pol Mini Din

App. 3.5.3 DC power input

Input voltage:	5 V DC ±5%
Max. power consumption when AccuScreen is docked:	5VA (5V, 1.0 A)
Max. power consumption when AccuScreen is not docked:	0.25 VA (5V, 50 mA)

App. 3.5.4 Power adapter

Type:	Wall-mount
Input voltage/range:	100-240 V AC, 50-60 Hz
Output voltage:	5.0 V DC
Output current:	Minimum 1.0 A
Mains plug types:	US, UK, Europe and Australia

App. 3.6 OAE probe

TEOAE

Type:	EP-TE from PATH Medical Gmbh

DPOAE

Type:	EP-DP from PATH Medical Gmbh

App. 3.6.1 Probe cable

Flexible, shielded cable, approx. length: 120 cm (approx. 55 inches)

App. 3.6.2 Dimensions

Probe body:	20 mm Ø x 23 x 11 mm (0.8” Ø x 0.9” x 0.43”)
Probe tip:	3.3 mm Ø x 10 mm (0.13” Ø x 0.4”)

App. 3.6.3 Weight

Probe incl. probe tip:	Approx. 4.5 grams

App. 3.6.4 Eartips

Standard (cylindric):	4 sizes (3.7 - 5 mm)
Tree tip:	1 size (4 - 7 mm)
Foam tip:	1 size (13 mm)

App. 3.7 ABR electrode cable

Type:	AECS-01 from PATH Medical Gmbh
	Flexible, shielded cable, approx. length: 140 cm (approx. 55 inches)

App. 3.8 ABR ear coupler cable (optional)

Type:	BAST-01 from PATH Medical Gmbh
	Flexible, shielded cable, approx. length: 145 cm (approx. 57 inches)

App. 3.9 Device class

IIa (according to Council Directive 93/42/EEC Appendix IX)

App. 3.10 Notes on EMC (Electromagnetic Compatibility)

- AccuScreen is part of a medical electrical system and is thus subject to special safety precautions. For this reason, the installation and operating instructions provided in this document should be followed closely.
- Portable and mobile high-frequency communication devices, such as mobile phones, may interfere with the functioning of AccuScreen.

Guidance and manufacturer's declaration - electromagnetic emissions for all equipment and systems

AccuScreen is intended for use in the electromagnetic environment specified below. The user of AccuScreen should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	AccuScreen uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	AccuScreen is suitable for use in all environments, including domestic environments and those directly connected to public low-voltage power supply networks that supply buildings used for domestic purposes

Guidance and manufacturer's declaration - electromagnetic immunity for all equipment and systems

AccuScreen is intended for use in the electromagnetic environment specified below. The user of AccuScreen should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV air	+/- 6 kV contact +/- 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_T is the AC power voltage prior to application of the test level.

Guidance and manufacturer's declaration - electromagnetic immunity - for equipment and systems that are not LIFE-SUPPORTING

AccuScreen is intended for use in the electromagnetic environment specified below. The user of AccuScreen should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Radiated RF IEC 61000-4-3	150 kHz to 80 MHz outside ISM bands [a] 3 V/m 80 MHz to 2.5 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of AccuScreen, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ for 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ for 80 MHz to 2.5 GHz, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). [b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [c] should be less than the compliance level in each frequency range. [d] Interference may occur in the vicinity of equipment marked with this symbol.

Note 1: At 80 MHz and 800 MHz the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

b. The compliance levels in the SMI frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

c. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which AccuScreen is used exceeds the applicable RF compliance level above, the AccuScreen should be observed to verify normal operation. If abnormal performance is observed, additional measures might be necessary, such as reorienting or relocating AccuScreen.

d. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and AccuScreen

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz outside ISM bands $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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